

**REMARKS**

Claims 1, 3-11, 14-16, 18-23 and 27-36 are currently pending in this application, with Claims 1 and 20 being independent. In this Amendment, Claims 1, 3-7, 9, 11, 14, 16 and 18-21 have been amended, Claims 2, 12-13, 17 and 24-26 have been cancelled without prejudice to or disclaimer of the subject matter contained therein, and new Claims 27-36 have been added. The specification and abstract have also been amended. All amendments presented herein are made for reasons of clarity with respect to the specification and drawings, and not for reasons related to the statutory requirements for patentability.

**THE DECLARATION**

The previously submitted Declaration was considered defective because the priority claim to U.S. Application Serial No. 09/958,933 should be made under 35 U.S.C. § 120 rather than 35 U.S.C. § 119, and the priority claim to U.S. Provisional Application Serial No. 60/133,876 should be made under 35 U.S.C. § 119(e). Applicant has addressed these concerns in the enclosed new Declaration, which properly indicates that the priority claim to U.S. Application Serial No. 09/958,933 is made under 35 U.S.C. § 120, and the priority claim to U.S. Provisional Application Serial No. 60/133,876 is made under 35 U.S.C. § 119(e).

**THE ABSTRACT**

The Abstract was objected to on the basis that it allegedly contained unnecessary phrases and legal phraseology. Without conceding the propriety of this objection, Applicant has addressed Examiner's concerns by amending the abstract to delete the first sentence and the expression "[t]he present invention provides," and to exclude the use of the term "comprise(s)." Accordingly, Applicant respectfully requests that the objection to the abstract be withdrawn.

**THE SPECIFICATION**

The specification was objected to for the reasons noted in the Office Action. Page 1, line 4, of the specification has been amended in accordance with the Examiner's suggestions. Specifically, it was amended to specify that U.S. Application Serial No. 09/958,933 has issued as U.S. Patent No. 6,582,964, and to replace the phrase "claiming priority" with the phrase "which claims priority--".

Accordingly, the Applicant respectfully requests that the objection to the specification be withdrawn in view of the amendments presented above.

### THE CLAIMS

Claims 1, 3-7, 9, 11, 14, 16 and 18-21 have been amended for the sake of improved clarity. Support for the amendments to the claims is provided, for example, at page 8 line 21 to page 14, line 4 of the specification, and by Figures 2, 3A-B, 4A-B and 5A-E.

New Claims 27-36 have been added to further define the invention of the present application, and to provide Applicant with a scope of protection commensurate with the disclosure. Claim 27 is based on cancelled Claim 26. Support for new Claims 28-30 is provided, for example, by Figures 3A, 4A and 5A. Support for new Claims 31-36 is provided, for example, at page 2, lines 15-27, and page 10, lines 16-25 of the specification. No new matter has been added.

### The Rejections Under 35 U.S.C. 112

Claims 1-26 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly failing to specifically point out and distinctly claim the subject matter of the present invention. The rejection of Claims 12, 17 and 24-25 has been rendered moot by the cancellation of these claims. Without conceding the propriety of the rejections, Applicant has amended Claims 1, 6-7, and 18 to remove the phrases that were considered objectionable in the Office Action.

Claims 1 and 24-25 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite, because the location of the cover plate in relation to the base plate and well was considered unclear. Without conceding the propriety of this rejection Applicant has amended Claim 1 to specify that the cover is hingedly connected to the base plate, and to specify that the cover plate has an open position, in which a sample may be introduced into the well of the sample tab, and a closed position, in which a bottom surface of a section of the cover plate covers the well. The rejection of Claims 24-25 has been rendered moot by the cancellation of those claims.

Claims 6 and 9 were also rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite, because the phrase "said containment wall" lacked antecedent basis. Without conceding the propriety of this rejection, Applicant has

addressed this rejection by amending Claims 6 and 9 to depend on Claims 5 and 3, respectively, instead of Claim 4.

Claims 6 and 17 were also rejected as allegedly being indefinite, because the location of the circular ring was unclear. Without conceding the propriety of this rejection, Applicant has addressed this rejection of Claim 6 by amending this claim to further specify that the locking member is disposed on the cover plate. Claim 17 was further rejected as allegedly being indefinite because the phrase "said containment wall" lacked antecedent basis. The rejections of claim 17 has been rendered moot by the cancellation of this claim.

Claim 20 was also rejected as allegedly being indefinite, because the recited step of closing the cover plate over the well was not considered consistent with the recited structure of the sample tab of Claim 1. Without conceding the propriety of this rejection, Applicant has obviated this rejection by amending Claim 1 to specify that the cover plate has a closed position, in which a bottom surface of a section of the cover plate covers the well.

Applicant respectfully requests that the rejections under 35 U.S.C. § 112, second paragraph, be withdrawn in view of the comments and amendments set forth above.

#### **The Rejections Under 35 U.S.C. § 102(b)**

##### **Valencia**

Claims 1, 20 and 24-26 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Valencia. As discussed above, Claims 24-26 have been canceled. With respect to Claims 1 and 20, Applicant submits the following remarks.

Valencia discloses a microscope slide 10 having a plurality of structurally defined retaining areas 12 (column 2, lines 43-45). Valencia also discloses that the slide 10 may be covered with a thin transparent overslip (see column 3, lines 53-56). The combination of the slide and overslip of Valencia differ, however, from the sample tab of the presently amended claims, which comprises a base plate and a cover plate that is *hingedly* connected to the base plate. Valencia does not teach or suggest that the disclosed overslip may be *hingedly* connected to the described slide. Claims 1 and 20, as amended, are, therefore, neither disclosed nor suggested by Valencia.

In view of the amendments and comments provided above, Applicant respectfully requests that the rejection under 35 U.S.C. § 102(b) over Valencia be withdrawn.

#### **Van Valkenburg**

Claims 1-2, 4, 6, 8, 12, 17, 19 and 24-25 have been rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Van Valkenburg. The rejection of Claims 2, 12, 17 and 24-25 has been rendered moot by their cancellation. With respect to Claims 1, 4, 6, 8 and 19, Applicant submits the following remarks.

Van Valkenburg discloses a device for collecting blood comprising a bowl 14 connected to a plate member 18, and a cap 27 attached by a flexible strap 27s secured to the outside of the bowl 14 (see column 4, lines 39-44; Figures 8 and 11). The bowl 14 has an opening 16 at its lower end for communicating with a capillary tube 20. The top of the bowl may be sealed by positioning the cap 27 over the top opening of the bowl, and snapping it over the perimeter of the top of the bowl (see column 5, lines 11-13).

The sample tab of the presently amended claims comprises a base plate defining a bottom surface of a well, and a cover plate that is *hingedly* connected to the base plate. The presently claimed sample tab differs from the blood-collecting device of Van Valkenburg in that the cover plate is hingedly connected to the base plate rather than to the well. Furthermore, the well of the presently amended claims is described as being defined by a top surface of a section of the base plate and by a wall extending from the top surface of the base plate. The bowl 14 of Van Valkenburg, however, is a *separate* component that is attached to plate member 18. In addition, the structure defining the well of the presently claimed sample tab differs from the bowl of Van Valkenburg in that it does not include an opening at its bottom surface. Claims 1, 4, 6, 8 and 19, as amended, are, therefore, neither disclosed nor suggested by Van Valkenburg.

In view of the amendments and comments provided above, Applicant respectfully requests that the rejection under 35 U.S.C. § 102(b) over Van Valkenburg be withdrawn.

### The Rejections Under 35 U.S.C. § 103(a)

#### Gavin et al. + Van Valkenburg

Claims 1-2, 4, 6, 8, 12, 17, 19 and 20-26 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Gavin et al. in view of Van Valkenburg. The rejection of Claims 2, 12, 17 and 24-26 has been rendered moot by the cancellation of these claims. With respect to Claims 1, 4, 6, 8, 19 and 20-23, Applicant submits the following remarks.

Gavin discloses a cuvette 12 having a supply reservoir 40 at one end thereof. The reservoir is cylindrical in shape and has an open top end to allow a person to supply blood into it, and an opening 51 at its bottom end that leads to a supply conduit 38 in fluid communication with conduits 30-34, which are used for conducting coagulation tests (see Figures 2 and 3a-b).

Van Valkenburg discloses a device for collecting blood comprising a bowl 14 connected to a plate member 18, and a cap 27 attached by a flexible strap 27s secured to the outside of the bowl 14 (see column 4, lines 39-44; Figures 8 and 11). The bowl 14 has an opening 16 at its lower end for communicating with a capillary tube 20. The top of the bowl may be sealed by positioning the cap 27 over the top opening of the bowl, and snapping it over the perimeter of the top of the bowl (see column 5, lines 11-15).

The sample tab of the presently amended claims comprises a base plate having a well, and a cover plate that is *hingedly* connected to the base plate. The presently claimed sample tab differs from the cuvette of Gavin and the blood-collecting device of Van Valkenburg in that it includes a cover plate hingedly connected to a base plate. Gavin does not teach or suggest that the disclosed cuvette 12 may include a cover for reservoir 40, and Van Valkenburg does not teach or suggest that the disclosed cap 27 may be hingedly connected to plate member 18.

Furthermore, the well of the presently amended claims is described as being defined by a top surface of a section of the base plate and by a wall extending from the top surface of the base plate. The well of the presently claimed sample tab, therefore, differs from the reservoir of Gavin and the bowl of Van Valkenburg in that it does not include an opening at its bottom surface. In addition, the well of the presently claimed sample tab differs from the reservoir of Gavin and the bowl of Van Valkenburg in that it has a bottom surface that is defined by a base plate. The bowl of

Van Valkenburg and the reservoir of Gavin are each *separate* components that are attached to a plate member and a cuvette, respectively.

Based on the above comments, even if the teachings of Gavin and Van Valkenburg are combined, and Applicant does not concede that they may be properly combined, one of skill in the art would not arrive at the sample tab of the presently claimed invention.

Accordingly, Applicant submits that Claims 1, 4, 6, 8, 19 and 20-23 are not unpatentable over Gavin et al. and Van Valkenburg. In view of the amendments and remarks set forth above, Applicant respectfully requests that this rejection under 35 U.S.C. § 103(a) be withdrawn.

Claims 7 and 18 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Gavin et al. in view of Van Valkenburg, and further in view of Kitrilakis et al. With respect to Claims 7 and 18, Applicant submits the following remarks.

The deficiencies of the combination of Gavin et al. and Van Valkenburg as discussed above are not remedied by further combination with Kitrilakis et al. Kitrilakis et al. discloses a device comprising a base plate 51 attached to a superposed plate 52, which has at one end a flexible hinge 53 connected to a hollow dome shell 54. The hollow dome shell 54 is held in a closed position relative to the base plate by a spring catch. When the catch is released, a capsule 59 containing detecting and heating structures for measuring blood gases can be positioned or removed (*see* column 3, line 57 to column 4, line 16; Figures 4-6). Kitrilakis et al. does not, however, disclose or suggest a cover plate for covering a well containing samples of analytes for spectroscopic measurement. Rather, Kitrilakis et al. discloses a hollow dome shell, which is used for frictionally retaining a capsule 59 containing electrodes used for measuring blood gases. Furthermore, the structure of the dome shell of Kitrilakis et al. would not permit a sample to be retained in a well within the base plate 52. As a result, one of skill in the art would not be motivated to combine the teaching of Kitrilakis et al. with that of Gavin et al. and Van Valkenburg.

Accordingly, Applicant submits that Claims 7 and 18 are patentable over the combination of Gavin et al. in view of Van Valkenburg, and further in view of Kitrilakis et al. In view of the amendments and remarks set forth above, Applicant respectfully requests that this rejection under 35 U.S.C. § 103(a) be withdrawn.

**Kheiri + Van Valkenburg**

Claims 1-6, 8-17, 19 and 24-25 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kheiri in view of Van Valkenburg. The rejection of Claims 2, 12-13, 17 and 24-25 has been rendered moot by the cancellation of these claims. With respect to Claims 1, 3-6, 8-11, 14-16 and 19, Applicant submits the following remarks.

Kheiri discloses a reagent test device 10 comprising a substrate 12 having a well-like semicrator 14 at one end (*see* Figures 1-2). A sample application site 20 consisting of a reagent pad or a transfer layer, such as a spreading layer or filter layer is present at the center of semicrator 14 (*see* column 3, lines 33-37).

Van Valkenburg discloses a device for collecting blood comprising a bowl 14 connected to a plate member 18, and a cap 27 attached by a flexible strap 27s secured to the outside of the bowl 14 (*see* column 4, lines 39-44; Figures 8 and 11). The bowl 14 has an opening 16 at its lower end for communicating with a capillary tube 20. The top of the bowl may be sealed by positioning the cap 27 over the top opening of the bowl, and snapping it over the perimeter of the top of the bowl (*see* column 5, lines 11-15).

The sample tab of the presently amended claims comprises a base plate having a well, and a cover plate that is *hingedly* connected to the base plate.

The presently claimed sample tab differs from the substrate of Kheiri and the blood-collecting device of Van Valkenburg in that it includes a cover plate hingedly connected to a base plate. Kheiri does not teach or suggest that the test device 10 may include a cover hingedly connected to substrate 12, and Van Valkenburg does not teach or suggest that the cap 27 may be hingedly connected to plate member 18.

Furthermore, the well of the presently amended claims is described as being defined by a section of the top surface of the base plate and by a wall extending from the top surface of the base plate. The well of the presently claimed sample tab, therefore, differs from the bowl of Van Valkenburg and the semicrator of Kheiri in that it has a bottom surface that is defined by a base plate. The bowl of Van Valkenburg is a *separate* component that is attached to a plate member, and has an opening 16 at its bottom end, which communicates with a capillary tube 20. The semicrator of Kheiri is defined by walls (16 and 18), which extend above the surface of the elongated substrate 12, and by a surface of a permeable reagent pad or a

transfer layer, and not by a surface of the elongated substrate 12. In addition, the structure defining the well of the presently claimed sample tab differs from the bowl of Van Valkenburg in that it does not include an opening at its bottom surface.

Based on the above comments, even if the teachings of Kheiri and Van Valkenburg are combined, and Applicants do not concede that they may be properly combined, one of skill in the art would not arrive at the sample tab of the presently claimed invention.

Claims 1, 3-6, 8-11, 14-16 and 19 are patentable over Kheiri and Van Valkenburg. In view of the amendments and remarks set forth above, Applicant respectfully requests that this rejection under 35 U.S.C. § 103(a) be withdrawn.

Claims 7 and 18 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kheiri in view of Van Valkenburg, and further in view of Kirilakis et al. With respect to Claims 7 and 18, Applicant submits the following comments.

The deficiencies of the combination of Kheiri and Van Valkenburg, as discussed above, are not remedied by further combination with Kirilakis et al. Kirilakis et al. discloses a device comprising a base plate 51 attached to a superposed plate 52, which has at one end a flexible hinge 53 connected to a hollow dome shell 54. The hollow dome shell 54 is held in a closed position relative to the base plate by a spring catch. When the catch is released, a capsule 59 containing detecting and heating structures for measuring blood gases can be positioned or removed (see column 3, line 57 to column 4, line 16; Figures 4-6). Kirilakis et al. does not, however, disclose or suggest a cover plate for covering a well containing samples of analytes for spectroscopic measurement. Rather, Kirilakis et al. discloses a hollow dome shell, which is used for frictionally retaining a capsule 59 containing electrodes used for measuring blood gases. Furthermore, the structure of the dome shell of Kirilakis et al. would not permit a sample to be retained in a well within the base plate 52. As a result, one of skill in the art would not be motivated to further combine the teachings of Kirilakis et al. with those of Gavin et al. and Van Valkenburg.

Claims 7 and 18 are therefore patentable over the combination of Kheiri in view of Van Valkenburg, and further in view of Kirilakis et al. In view of the amendments and remarks set forth above, Applicant respectfully requests that this rejection under 35 U.S.C. § 103(a) be withdrawn.

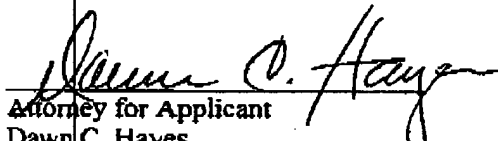


**CONCLUSION**

Applicant respectfully submits that the present application is in condition for allowance and a notice to that effect is earnestly solicited.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should be directed to our address given below.

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